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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC.; CYTYC CORPORATION; and HOLOGIC LP, Plaintiffs, v. SENORX, INC., Defendant.	No. C-08-00133 RMW ORDER CONSTRUING CLAIMS OF UNITED STATES PATENT NOS. 5,913,813, 6,413,204 AND 6,482,142 **[Docket Nos. 130, 134, 141 and 144]**

On October 15, 2008, the Court held a claim construction hearing on the dispute between the parties as to the construction that should be given to certain terms and language in the claims of United States Patent Nos. 5,913,813 ("'813 patent"), 6,413,204 ("'204 patent"); and 6,482,142 ("'142 patent"). After consideration of evidence presented and the relevant portions of the record and after hearing the arguments of the parties, the Court construes the disputed terms and language as set forth below.

I. BACKGROUND

The parties develop products for use in breast brachytherapy. Brachytherapy is a form of radiation therapy whereby a radioactive source is placed inside or near an area requiring treatment.

For breast brachytherapy, breast tumors are removed via a lumpectomy procedure and a device for delivering radiation is placed in the tumor cavity. The goal of such a treatment is to more efficiently deliver radiation to any remaining cancerous tissue while minimizing damage to healthy tissue.

Plaintiffs Hologic, Inc., Cytyc Corporation, and Hologic L.P. (collectively "Hologic") own the patents-in-suit and manufacture and sell a balloon brachytherapy device known as the MammoSite Radiation Therapy System ("MammoSite"). Defendant SenoRx, Inc. ("SenoRx") also markets a balloon brachytherapy device known as the Contura Multi-Lumen Balloon ("Contura") which allegedly infringes Hologic's patents and competes with Hologic's MammoSite.

It is undisputed that the general structure and use of the MammoSite and Contura are the same. Both devices consist of a catheter body with an inflatable balloon on one end. Both devices are implanted into the lumpectomy cavity of a breast. Treatment of the breast involves inflating the balloon portion of the device with a contrast fluid to hold it in place and to conform the cavity to the shape of the balloon and delivering a radiation source (a radioactive seed) through a lumen.

Hologic's MammoSite device has a single central lumen by which the radiation source may be placed within the balloon; the SenoRx Contura device accused of infringing has multiple lumens for placing radiation sources. Specifically, the Contura has five lumens, one straight central lumen and four surrounding curved lumens, into which radiation source wires can be inserted.[1] The infringement issue, of course, is whether the Contura infringes Hologic's patents, not whether it contains the same elements as the MammoSite.

All three patents-in-suit are related. The '813 patent is the parent. The '204 and '142 patents are continuations-in-part of the '813 patent. The '813 patent relates to an invention comprising a concentric arrangement of an inner spatial volume and an outer spatial volume defined by an inflatable chamber, disposed near the distal end of a catheter body. The '204 patent is directed toward an apparatus for brachytherapy used to irradiate interstitially diseased cells within the tissue surrounding the cavity created by the surgical removal of diseased tissue. The device of the '204

[1] SenoRx asserts that the Contura can be either used as a "single-dwell" device such that only one radioactive source is inserted into one of the lumens or a "multi-dwell" device such that a radioactive source can be inserted into more than one of the lumens.

patent also contains a inner spatial volume located inside an outer, expandable surface (e.g., a balloon). The '142 patent is directed toward a device capable of producing asymmetrically-shaped dose profiles.

Hologic asserts that the Contura device infringes Claims 11 and 12 of the '813 patent, Claims 4 and 17 of the '204 patent, and Claims 1 and 8 of the '142 patent. SenoRx asserts that it does not infringe those claims and that Claims 1 and 8 of the '142 patent are invalid because they are inoperable and not enabled. Claim 1 of the '142 patent is an independent claim and the others at issue are dependent claims which incorporate disputed language from other claims. Some of the terms or language needing construction first appear in claims that are not asserted but are incorporated into one or more of the claims at issue.

The parties dispute the meaning of several terms and phrases in the claims. In earlier litigation between Hologic (then Cytyc) and Xoft, Inc. concerning infringement and validity of the '813 and '204 patents (Case No. C-05-05312 RMW and referred to herein as the "*Zoft* case"), the Court construed some of the claim terms disputed in the instant case. Courts in this district have been willing to consider a prior claim construction but have stressed the importance of conducting an independent inquiry. *See Visto Corp. v. Sproqit Techs., Inc.*, 445 F. Supp. 2d 1104, 1108-09 (N.D. Cal. 2006) (Chen, M.J.); *Townshend Intellectual Property, L.L.C. v. Broadcom Corp.*, 2008 WL 171039 (N.D. Cal. Jan. 18, 2008) (Fogel, J.) (modifying prior claim construction in light of a new party's arguments). This general practice allows a fresh look at a claim construction with the benefit of the prior court's understanding and construction of the patent. *See e.g., Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1329 (Fed. Cir. 2008). Indeed, the Federal Circuit has said that it "would be remiss to overlook another district court's construction of the same claim terms in the same patent as part of [a] separate appeal." *Id.* In *Finisar*, the Federal Circuit found a second district court's claim interpretation particularly helpful where it referred back to the prior construction and noted where it disagreed. *Id.* The lesson from *Finisar* is that additional litigation can refine and sharpen the court's understanding of an invention and that a second trial court should *not* defer to an earlier trial court's claim construction without questioning its accuracy. This is

particularly true here where the earlier case was before the same judge and settled before trial and thus before the claim construction became final.

II. CLAIM CONSTRUCTION

Construction of a patent, including terms of art within a claim, is exclusively within the province of the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996). In determining the meaning of a disputed claim limitation, the intrinsic evidence, including the claim language, written description, and prosecution history, is the most significant. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Words of a claim "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art. *Id.* at 1312-13. Claims are read in view of the specification, which is the "single best guide to the meaning of the disputed term." *Id.* at 1315. A court "should also consider the patent's prosecution history, if it is in evidence." *Id.* at 1317. Finally, although it is generally less significant than the intrinsic record, extrinsic evidence can "shed useful light on the relevant art." *Id.*

A. Disputed Construction of Terms of '813 and '204 Patents

1. Predetermined Spacing

Claim 1 of the '813 patent requires "predetermined *constant* spacing between said inner spatial volume and the radiation transparent wall." (Emphasis added). Before the claim construction hearing the parties stipulated, and the Court agrees, to construe the claim to require a "fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (i.e., the inner spatial volume and the outer chamber are concentric and the same shape)."

But the Court must still construe the language in Claim 3 of the '204 patent which describes an apparatus "wherein a predetermined spacing is provided between said inner spatial volume and the expandable surface." The parties propose the following definitions.

Term	Hologic	SenoRx
"Predetermined spacing"(Claim 1 of '813 patent and Claim 3 of '204 patent)	the distance between the inner spatial volume and the expandable surface element is determined in advance	same construction as given "predetermined constant spacing" in Claim 1 of '813 patent

Hologic argues that, because Claim 3 does not include the word "constant," it should not be read into the claim. Pls.' Reply Claim Construction Brief 4 (citing *Forest Labs, Inc. v. Abbot Labs*, 239 F.3d 1305, 1310 (Fed. Cir. 2005)("Where claims use different terms, those differences are presumed to reflect a difference in the scope of the claims.")). But here the intrinsic evidence strongly suggests that "predetermined spacing" as used in the '204 patent also requires the distance between the wall of the inner spatial volume and the outer expandable surface to be constant. First, the '204 patent's embodiments incorporate those in the '813 patent, each of which includes constant spacing. '204 Patent 1:8-11; 3:61-65; 4:61-67; 5:27-28.

Additionally, Claim 1 of the '204 patent requires that the three-dimensional isodose profile be in "substantially similar shape to the expandable surface element," which the Court construes to require that the isodose profile be concentric with the expandable surface. *See infra*. Under Claim 1 of the '204 patent and Claim 3 of the '813 patent, the inner spatial volume and the radiation source inside produce the isodose profile, and the outer expandable surface attenuates the produced radiation. Thus, the inner spatial volume must be concentric with and constantly spaced from the outer expandable surface if the radiation profile is to be the same shape as the outer surface. This is the same geometric arrangement that the parties stipulated was required by the "predetermined constant spacing" limitation in Claim 1 of the '813 patent. The Court accordingly construes "predetermined spacing" in Claim 3 of the '204 patent to have the same meaning as "predetermined constant spacing" in Claim 1 of the '813 patent.

2. Three-dimensional Isodose Profile

Claim 1 of the '204 patent requires a "radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element." Claim 17 of the '204 patent recites "[t]he apparatus of claim 1,

wherein the radiation source is a plurality of solid radiation sources arranged to provide an isodose profile having a shape substantially similar to the shape of the outer spatial volume." The parties propose the following constructions:

Term	Hologic	SenoRx
"three dimensional isodose profile that is substantially similar in shape to the expandable surface element" (Claim 1 of '204 patent) "Isodose profile having a shape substantially similar to the shape of the outer spatial volume (Claim 17 of '204 patent)"	No construction necessary	A *final* three-dimensional isodose profile that is substantially the same shape as the outer spatial volume expandable surface and is *concentric* with the outer spatial volume expandable surface (emphasis added)

SenoRx seeks a construction requiring that: (1) the isodose profile referred to must be the final isodose profile delivered to the tissue; and (2) the isodose profile must be substantially the same shape as, and concentric with, the outer surface.

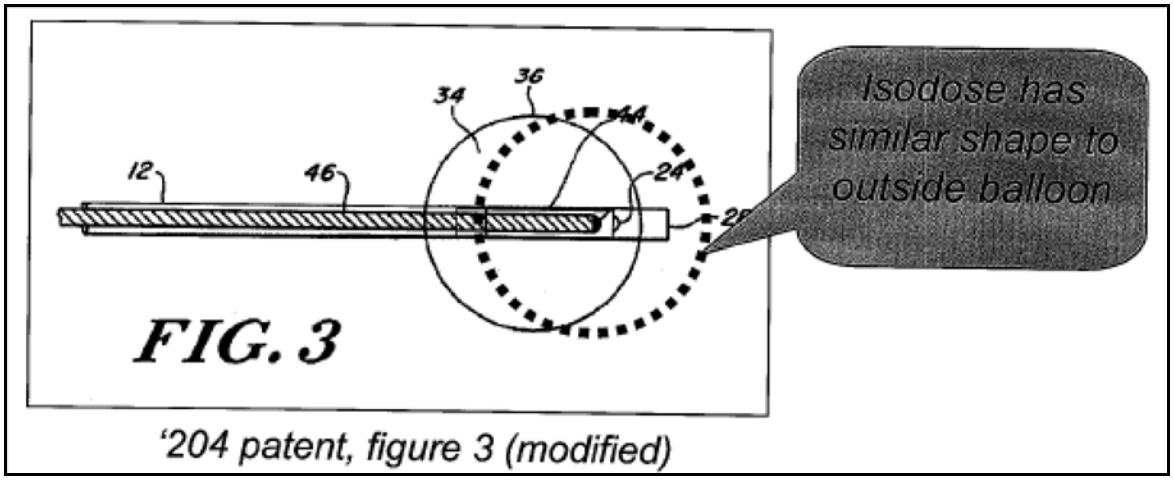
According to SenoRx the "absorbed dose" is the final, total dose resulting from the delivery of radiation and absorbed by the tissue at the end of radiation therapy. SenoRx states that the focus of the invention is on achieving a "predetermined dose range" in the target tissue, defined as the dose "between a minimum prescribed absorbed dose for delivering therapeutic effects to tissue that may include cancer cells, and a maximum prescribed absorbed dose above which healthy tissue necrosis may result." '204 patent 2:46-55. Thus, according to SenoRx, the "isodose profile" must be the final, cumulative dose.

Hologic disagrees, arguing that SenoRx is mischaracterizing the purpose of the invention in order to improperly limit the claim. According to Hologic, the '204 patent describes two primary purposes of the invention: to provide a uniform radiation dose to the targeted tissue and to ensure a predetermined dose range so that only cancerous tissue is destroyed by the radiation. Neither of these purposes requires that the isodose profile refer to the accumulated final dose. Indeed, as Hologic contends, one skilled in the art would understand and expect that the desired therapeutic result may call for the dose profile to be modified or adjusted. The Court agrees with Hologic that

as used here, it is not appropriate to interpret the isodose profile as limited to a final, cumulative absorbed dose.

SenoRx also contends that the claim language requiring that the isodose profile be substantially the same shape as the outer expandable surface requires that the two be concentric. SenoRx points out that the specification describes the dose profile as "within the target tissue at points equidistant from the surface of the outer spatial volume should be substantially uniform in substantially every direction." '204 Patent 5:13-19. Further, in distinguishing the '204 patent over the prior art, the applicants stated that the prior art did not have balloons that were equally spaced apart and therefore could not create an isodose profile that had substantially the same shape as the outer element. See Ex. 9, Dec. 20, 2000 Am., '204 Prosecution History. The prior art showed a figure that had two balloons but the inner balloon was positioned off center from the outer balloon.

Hologic contends that the specification language and prior art distinction do not require that the expandable surface be concentric with the isodose profile. It is possible, Hologic argues, to have an isodose profile that is substantially similar in shape as, but not concentric with, the expandable surface. Hologic suggests that a single radiation source enclosed in an expandable spherical outer surface and distributed off center but on the longitudinal axis would have a such a dose profile. This arrangement is shown in Hologic's claim construction presentation diagram below:



'204 patent, figure 3 (modified)

The dotted line in the above diagram is meant to represent the shape of the isodose profile. But the isodose profile refers to levels of equal dose delivered to tissue, and in the above diagram the

radiation would be subject to the attenuating material in different degrees. Because the source is positioned off center, the radiation at the distal end would be attenuated less than that at the proximal end. In the above diagram, the dotted line on the right of the diagram would be closer to the wall of the inner chamber. Hologic's diagram is thus not an example of a similarly shaped but non-concentric isodose profile. Indeed, any isodose profile that is non-concentric with the expandable surface would be asymmetrically attenuated in the same way. Thus, the requirement that the isodose profile be the same shape as the expandable outer surface also requires that the two be concentric.

Accordingly, the Court finds construes the term "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element" to mean "three-dimensional isodose profile that is substantially the same shape as the outer spatial volume expandable surface and is concentric with the outer spatial volume expandable surface."

3. Inner Spatial Volume

As set forth above, Claim 1 of the '813 patent claims "an inner spatial volume disposed proximate the distal end of the catheter body member." Claim 1 of the 204 patent also requires "an inner spatial volume disposed proximate to the distal end of the catheter body member." The parties propose the following constructions:

Term	Hologic	SenoRx
"inner spatial volume" (Claim 1 of '813 patent and Claim 1 of '204 patent)	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide	a region of space surrounded by an outer spatial volume and either enclosed by a distensible polymeric film wall or defined by the outside surface of a solid radionuclide sphere

The parties disagree about (1) whether the polymeric film wall must be distensible; and (2) whether the solid radionuclide must be spherical. In *Xoft*, the Court looked to the specifications of the '813 and '204 patents for a definition and concluded that "[i]n all embodiments . . . the boundary of the inner volume is either a polymeric film wall or the edge of a solid sphere." Accordingly, the Court construed "inner spatial volume" as an inner volume that is "either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere." SenoRx contends that

the "inner spatial volume," when defined by a polymeric film wall, must be further limited to a "distensible" polymeric film. With respect to the definition of an "inner spatial volume" that is defined by outside wall of a solid radionuclide, Hologic argues that the outside surface need not be spherical.

SenoRx supports its proposed "distensible" requirement by pointing to the specification of the '204 patent for support. For example, the summary of the invention states: "In different embodiments, the inner spatial volume can be defined by a distensible polymeric wall containing radioactive source material . . . ." '204 patent, col. 2:56-60. Different embodiments also describe distensible polymeric film walls. *See id.*, col. 3:66-col.4:3. The '813 patent also contains a distensible chamber. '813 patent, Abstract; col. 3:39-41. Finally, SenoRx contends that non-distensible polymeric walls are not described in the patents and the inventors did not conceive of such an invention.

Hologic asserts that adding "distensible" improperly narrows the claim to a preferred embodiment. Additionally, the '813 and '204 patents both suggest use of non-distensible walls. For example, in describing the preferred embodiment, the patents recite that "[a]ffixed to the tubular body proximate to the distal end thereof is an inner spatial volume which *may* be defined by a generally spherical polymeric film wall." '813 patent, col. 2:33-36; '204 patent, col. 3:57-59 (emphasis added). The specification does not say that the polymeric wall must be "distensible." Additionally, Hologic contends that the claims were broadened during prosecution to eliminate the "distensible" requirement. Ex. I at 1,2. The claims as originally filed recited that the "inner spatial volume is an inner closed, distensible chamber." The "distensible" requirement was subsequently removed so that the claim called for an "inner spatial volume" that "is an inner closed chamber." Finally, Hologic notes that the "distensible" requirement is a limitation only used in certain claims. For example, Claim 9 of the '204 patent states "wherein the inner spatial volume is an inner closed distensible chamber defined by a further radiation transparent wall."

The intrinsic record does not support importing the limitation of the term "distensible" into the definition of "inner spatial volume." Accordingly, the Court does not construe the term to require "distensible" polymeric film walls.

SenoRx also contends that the radionuclide must be a sphere. SenoRx argues first that the only solid radionuclide described in the '813 and '204 patents is a spherical one. For example, the '204 patent describes using a solid spherical radiation emitting material as the inner spatial volume. It specifically refers to radioactive micro spheres of the type available from the 3M Company of St. Paul, Minnesota as ones that could be used. '204 patent, col. 4:44-50. Similarly, the '813 patent states that "a solid spherical radiation emitting material" can be the "inner spatial volume." '813 patent, col. 2:56-63. SenoRx argues that because the inventions generally use a spherical outer balloon, the radionuclide must be spherical to preserve the constant spacing between the inner volume and outer and yield a uniform radiation profile. If a non-spherical radionuclide were enclosed in an outer volume of the same shape, SenoRx asserts that the dose distribution would still be non-uniform because of the greater self-absorption of a solid non-spherical radionuclide in a longitudinal direction than in other directions. Orton Decl. ¶ 24.

Hologic contends that the radionuclide does not need to be spherical. Hologic asserts that the intrinsic evidence supports its position. For example, the patents state that "[i]t is not essential to the invention that the chambers 30 and 34 [the inner and outer volumes] have spherical walls . . . ." '813 patent, col. 3:9-10; '204 patent, col. 5:13-16. Additionally, the patents describe radioactive particles as solids. *See* '813 patent, col. 3:3; col. 4:6-7. Hologic also points to Claim 13 of the '813 patent as evidence that the patentee could impose a spherical limitation but chose not to.

Each expert asserts that one of ordinary skill in the art would support his understanding of the shape of the solid radionuclide. Dr. Orton suggests that a person of ordinary skill in the art would know that a non-spherical source would yield a non-uniform dose distribution. Orton Decl. ¶ 24. Dr. Verhey, on the other hand, states that a person of ordinary skill in the art would know that "in a typical brachytherapy procedure using a solid radionuclide, the radionuclide is not necessarily spherical in shape and does not need to be." Verhey Decl. 3:27-4:1

The intrinsic evidence shows that spherical radionuclide solids were contemplated, not required. Furthermore, Dr. Orton's testimony concerning the ordinary skill in the art is hard to square with the pill-shaped inner volume in Figure 3 of the '813 patent, which would seemingly be

subject to the same longitudinal self-absorption – and resulting non-uniform dose profile – as a non-spherical radionuclide solid.

The Court adopts Hologic's proposed definition of "inner spatial volume": "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide."

4. Means . . . For Rendering Uniform the Radial Absorbed Dose Profile

As set forth above, Claim 1 of the '813 patent requires a "means disposed in the other of the inner spatial volume and outer chamber for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides." The parties propose the following constructions:

Term	Hologic	SenoRx
"means . . . for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides" (Claim 1 of '813 patent)	Function: making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument Structure: a radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents	Function: making the absorbed dose of radiation substantially more uniform between the surface of the outer chamber and a predetermined depth in the target tissue Structure: a radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, the gas barium sulfate, or their equivalents, that performs this function by absorbing or attenuating radiation

The parties agree that this is a means-plus-function claim limitation. As such, the function must be construed and the corresponding structure or its equivalent identified in the specification. *BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovensm L.C.C.*, 303 F.3d 1332, 1343 (Fed. Cir. 2002). The parties also agree that the structure is "a radiation absorbing or attenuating material." However, the parties dispute whether the material must actually absorb radiation, which is SenoRx's position, or whether the limitation is satisfied provided the material is present and the function is performed, for example, by merely the space occupied by the absorbing material, which is Hologic's

position. The parties also dispute whether the function requires that the absorbing material makes the dose "substantially more uniform" as opposed only to "more uniform."

SenoRx asserts that the absorbing or attenuating material can, and is meant to, affect the dose curve by actually absorbing or attenuating the radiation and, therefore, the identified structure in the specification must perform the claimed function by actually absorbing or attenuating the radiation. SenoRx points to one embodiment of the '813 patent which provides the radioactive material in the outer balloon and the radiation absorbing material in the inner balloon. '813 patent, col. 3:51-65. SenoRx asserts that in this configuration, the radiation-absorbing material is not performing the function of spacing the radiation from the tissue. The patent states that the radiation attenuation fluid in the inner chamber can affect the slope of the radiation curve. *Id.* at col. 3:51-56. Thus, SenoRx argues that in order for the claim to apply to all embodiments, the radiation absorbing or attenuating material identified by the specification as the "structure" for performing the claimed function must perform the function by absorbing or attenuating radiation. *See* Orton Decl. ¶ 38.

Hologic does not contest SenoRx's description of the embodiment. But Hologic does argue that SenoRx's proposed construction improperly imports an unclaimed function into the means-plus-function claim, and that SenoRx is defining the function to require more than is claimed. *See Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 448 F.3d 1324, 1334 (Fed. Cir. 2006)(stating that it is improper to "import[] unclaimed functions into a means-plus-function claim" by "defining a claimed function to require more than is actually claimed."). Hologic contends that the claim language does not recite a specific mechanism by which the function of "rendering uniform . . ." is performed. Further, Hologic asserts that the prosecution history does not clearly state that the "means . . . for rendering uniform" must include the function of attenuating or absorbing radiation.

The Court reads the limitation as only requiring that the structure fulfill the function of rendering the absorbed dose more uniform. Whether the structure performs this function by absorbing radiation or by mere spacing is not dictated by the limitation.

SenoRx further asserts that the proposed construction requires the dose profile to be rendered "substantially" more uniform, rather than simply "more uniform" as the Court construed the term to mean in *Xoft*. In *Xoft*, the Court determined that rendering the dose uniform in an absolute sense

was not possible. However, SenoRx argues that while this is correct, "rendering uniform" should not be construed to cover rendering the dose "slightly more uniform." Thus, asserts SenoRx, "substantially more uniform" is consistent with the Court's rationale in *Xoft* and more accurately reflects the use of the term in the claim and prosecution history.

Hologic contends that SenoRx's proposed construction makes the term more ambiguous. The function can be made clear by explaining that the rendering more uniform function is to reduce or prevent necrosis in healthy tissue at or close to the outer wall of the instrument. Rendering the profile "more uniform" is sufficient.

The Court adopts the following construction for the means-plus-function claim limitation: Function: making the absorbed dose of radiation more uniform to reduce or prevent necrosis in healthy tissue at or close to the outer wall of the instrument. Structure: a radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents.

5. Inner Closed, Chamber

The term "inner closed, chamber" is found in Claim 2 of the '813 patent, on which asserted Claim 11 depends. Claim 2 recites an "inner spatial volume" that is "an inner closed, chamber." The parties propose the following construction:

Term	Hologic	SenoRx
"inner closed, chamber" (Claim 11 of '813 patent)	No construction necessary	A compartment located completely inside of the outer chamber and closed off within the outer chamber

Hologic asserts that no construction of this term is necessary. SenoRx contends that the "inner closed, chamber"must be completely inside the outer chamber and closed off from the outer chamber. Hologic points out that this is not possible. If the chamber were closed off, there would be no way of getting radioactive material into or out of the inner chamber. The Court interprets the term to only require that the inner spatial volume be a closed chamber that is located inside the outer chamber. Accordingly, the Court agrees with Hologic that the term does not require construction.

B. Disputed Construction of Terms of '142 Patent

Hologic asserts that SenoRx infringes Claims 1 and 8 of the '142 patent.[2] Claim 1 recites:

> 1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:
>
> an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;
>
> a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.

'142 patent 61-9:6. Claim 8 states:

> 8. The apparatus of claim 1, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

Id. at 13-17.

The parties dispute the meaning of several of the terms of the claims.

1. Apparatus Volume

The term "apparatus volume" appears in Claim 1 of the '142 patent. Claim 1 recites "a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated." *Id.* at 8:63-67. The parties propose the following constructions:

Term	Hologic	SenoRx
"apparatus volume" (Claim 1 of '142 patent)	A three-dimensional geometric solid composed of an expandable outer surface	The three-dimensional region of space within the expandable outer surface

The construction of this term is discussed in this Court's order denying defendant's motion for summary judgment that the '142 patent is invalid filed concurrently with this order.

2. Located So as to Be Spaced Apart from the Apparatus Volume

[2] Hologic had asserted Claim 6 against SenoRx. On May 30, 2008, Hologic informed SenoRx that it was dropping its assertions of infringement of Claim 6.

Claim 1 of the '142 patent requires "a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume." *Id.* at 9:1-3. The parties propose the following constructions:

Term	Hologic	SenoRx
"located so as to be spaced apart from the apparatus volume"(Claim 1 of '142 patent)	located so as to be not on or touching the apparatus volume	located outside (i.e., not within) the apparatus volume

The construction of this language is dependent on being able to sensibly construe the term "apparatus volume" discussed above. The meaning of this language is also discussed in this Court 's order denying defendant's motion for summary judgment that the '142 patent is invalid.

3. Predetermined Asymmetric Isodose Curves

This term appears in asserted Claims 1 and 8 of the '142 patent. For example, Claim 1 requires "the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume." *Id.* at 9:3-6. The parties propose the following constructions:

Term	Hologic	SenoRx
"predetermined asymmetric isodose curves"(Claim 1 of '142 patent)	predetermined isodose curves that are not symmetric with respect to the longitudinal axis of the apparatus volume	isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume

SenoRx asserts that its proposed definition is more consistent with the claim language. SenoRx asserts that Hologic's proposed construction, in particular "the longitudinal axis" limitation, is a limitation found in some but not all of the embodiments of the patent and thus should not be part of the construction of the term. SenoRx points to the specification that states:

> The present invention solves the problems described above by providing an interstitial brachytherapy apparatus for delivering radioactive emissions in an asymmetric fashion to target tissue surrounding a surgical extraction site. . . .

Id. at 2:56-59.

> *In one configuration, asymmetric isodose curves* are created in the target tissue by shaping or locating the radiation source so as to be asymmetrically placed *with respect to a longitudinal axis of the apparatus*. . . .

Id. at 2:65-3:1.

> *In another example*, the radiation source comprises a plurality of spaced apart solid radioactive particles disposed within the apparatus volume and *arranged to provide a predetermined asymmetric isodose curve within the target tissue*.

Id. at 3:7-11 (emphasis added). Asymmetry in the isodose curves, SenoRx argues, need not be limited to longitudinal asymmetry. SenoRx further points to Claim 6, which explicitly requires an elongated member "shaped to provide asymmetric placement of a radiation source with respect to a longitudinal axis through the apparatus volume." Thus, asserts SenoRx, when the inventors intended to define asymmetry with respect to the longitudinal axis of the device, they did so explicitly. Finally, SenoRx points to the testimony of Hologic's expert Dr. Verhey who testified as follows:

> Q. Is the radiation profile that is provided by the embodiment of Figure 3 asymmetric with respect to the longitudinal axis of the device?
>
> A. No, actually, it's not with respect to the longitudinal axis.

Verhey Depo Tr. at 146:13-17.

Hologic asserts that SenoRx's proposed construction is incorrect. Hologic asserts that the radiation sources in the claims are arranged asymmetrically so as to not be on the longitudinal axis and it is a direct result of this arrangement that creates the "predetermined asymmetric isodose profile." Hologic looks to the specification for support, including the same language cited by SenoRx. Hologic also explains that Dr. Verhey made a mistake during his deposition.

It does appear Dr. Verhey may have made a mistake with respect to Figure 3. However, although the specification and claims frequently refer to symmetry with respect to the longitudinal axis, they do not always do so. Claim 6 does include a specific requirement that the asymmetry be longitudinal. The patentee did not do so in Claims 1 and 8. No express limitation suggests that those claims require configurations with isodose curves that are asymmetric only with respect to the longitudinal axis. The Court therefore interprets "predetermined asymmetric isodose curves" to mean "isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume."

4. Asymmetrically Located and Arranged Within the Expandable Surface

Claim 1 of the '142 patent requires "a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface." *Id.* at 9:1-5. The parties propose the following constructions:

Term	Hologic	SenoRx
"asymmetrically located and arranged within the expandable surface"(Claim 1 of '142 patent)	located and arranged so as not to be on the longitudinal axis of the expandable surface	located and arranged inside the expandable surface so as not to be concentric with the expandable outer surface

Because "predetermined asymmetric isodose curves" is not limited to longitudinal asymmetry, the Court here also adopts SenoRx's construction. Hologic argues that the two parts of Claim 1 should be separately construed. However, limiting the scope to longitudinally asymmetrically placed radiation sources would have the result of equivalently constraining the dose profiles. That is, the asymmetry in the dose mirrors the asymmetry in the source-placement. Hologic further advances no intrinsic evidence to distinguish the meaning of the "asymmetrically" when addressing the location of the radiation source and "asymmetric" when describing the isodose profile.

D. Disputed Construction of Terms Contained in All Three Patents

1. Plurality

All three patents contain claim terms requiring that a "a plurality of radioactive solid particles" or a "plurality of solid radiation sources" be placed in the inner spatial volume. The parties propose the following constructions:

Term	Hologic	SenoRx
"plurality of radioactive solid particles" ('813 patent, Claim 12)	No construction necessary	Two or more separate radioactive particles placed in the inner spatial volume at the same time
"plurality of solid radiation sources" ('204 patent, Claim 17)	No construction necessary	Two or more separate radioactive solid sources placed in the inner spatial volume at the same time

"plurality of solid radiation sources" ('142 patent, Claim 6)	No construction necessary	Two or more separate radioactive solid sources placed within the expandable outer surface at the same time

SenoRx asserts that the plain meaning of "plurality" requires that two or more separate radioactive solid sources be placed in the inner spatial volume at the same time. Hologic does not dispute that "plurality" means two or more. However, Hologic does dispute that the claim requires two or more separate radionuclide sources be placed in the inner spatial volume at the same time. By requiring that discrete radiation sources be present and used simultaneously, Hologic argues that SenoRx's proposed construction seeks to import aspects of preferred embodiments into the claims. Nothing in the claims requires the "plurality" of radiation sources to be present in the device at the same time, according to Hologic, and, therefore, the claims which teach emitting therapeutic rays from more than one location to achieve "a desired composite radiation profile" can be achieved by moving a radiation source to multiple locations at different times. Hologic contends that at the time of the filing of the '813 patent the remote afterloaders necessary to practice the multi-core embodiment depicted in Fig. 5 of the '813 patent and Fig. 4 of the '204 patent did not exist. *See* Verhey Decl. 29. However, remote afterloaders capable of stepping a single radionuclide through multiple locations within a brachytherapy balloon applicator were available. Therefore, Hologic asserts that the claim language was intended to cover an embodiment where a radionuclide is moved sequentially to multiple locations as well as that of multiple radionuclides at fixed locations.

Hologic's arguments are confusing. While seeming to admit that "plurality" requires two or more radiation cites, Hologic then appears to argue that the claim term covers a single radioactive seed inserted into different lumens at different times. SenoRx's proposed construction is supported by the intrinsic evidence. The specifications of the patents distinguish a single radiation source from a plurality of separate radiation sources. For example, the '813 patent discloses that "[i]n different embodiments, the inner spatial volume can be defined by a distensible polymeric wall containing radioactive source material which can be a fluid material, by *a* solid radioactive source, or by a region containing a plurality of solid radioactive *sources*." '813 patent 2:64-66; *see* '204 patent col. 3:33-35 ("Fig. 4 is an additional embodiment of an interstitial brachytherapy apparatus of the

invention having a radiation source comprising a plurality of solid radiation *particles*"); '142 patent col. 5:18-20 (the asymmetrically shaped isodose curve may be created by providing a plurality of solid radioactive *particles* on a curved wire . . . .)(emphasis added). In all of these examples, the plurality of radioactive sources or particles are being used at the same time. There is no discussion in any of the patents of a plurality of radioactive sources being used at different times. Accordingly, the Court adopts SenoRx's proposed construction.

E. Additional Terms

After filing claim construction briefs, the parties jointly submitted supplemental claim construction briefs requesting construction of additional terms, specifically (1) "radial absorbed dose profile" ('813 patent, Claim 1); (2) "uniform radiation profile" ('813 patent, Claim 1); (3) "the expandable outer surface element is . . . adapted to contact tissue . . . and conform the tissue. . . ." ('204 patent, Claim 4); (4) "the expandable outer surface is sufficiently rigid to deform the target tissue" ('142 patent, Claim 8); and (5) "predetermined asymmetric isodose curves . . . " ('142 patent, Claims 1 and 8). SenoRx asserts that Hologic's expert, Dr. Verhey, presents new constructions of these additional terms that Hologic plans to offer at trial, thus requiring the SenoRx to request the court to construe the additional language. Hologic asserts that Dr. Verhey has not provided new constructions in his expert report, contrary to Senorx's assertion, and argues that the disputed language should be construed in accordance with its plain meaning. Hologic contends that its proposed construction of these additional terms adopts the Court's construction in the *Xoft* case.

1. Uniform Radial Absorbed Dose Profile; Uniform Radiation Profile

The term "radial absorbed dose profile" appears in limitation (e) of Claim 1 of the '813 patent. The term "uniform radiation profile" appears in the preamble of Claim 1. The preamble is not limiting because it merely sets forth the intended use of the invention and a structurally complete invention is described in the claim body. *Catalina Marketing International, Inc. v. Coolsavings*, 289 F.3d 801, 808 (Fed. Cir 2002). Even if the preamble were construed to add a limitation, there is no basis for distinguishing the meaning of "uniform" in the preamble from its meaning in the means-plus-function limitation (e). The parties assert the following interpretations of the term "radial absorbed dose profile":

Term	Hologic	SenoRx
"radial absorbed dose profile" (Claim 1 of '813 patent)	no construction necessary	The "radial absorbed dose profile" means the absorbed dose as a function of distance in a radial direction from the outer surface of the radiation transparent wall. "Uniform" does not require that the tissue and the balloon conform to each other or relate to the shape of the isodose

In his expert report on behalf of Hologic, Dr. Verhey opines that the term "uniform" used in the preamble and the limitation (e) of Claim 1 of the '813 patent requires that the tissue and the outer balloon conform to each other: "It is critical to the claimed invention that the tissue and the balloon conform to each other–this is the primary way to achieve a 'uniform' dose." Verhey Expert Report, p. 39. Hologic argues that this interpretation is implicit in the Court's interpretation in the *Xoft* case, specifically that "rendering uniform" is "to make the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument." *Xoft* Claim Construction Order filed April 27, 2007.[3]

SenoRx argues that this construction of "uniform" in the claim limitation 1(e) of the '813 patent is inconsistent with the Court's and Hologic's prior construction, and is not supported by the teachings of the '813 patent. SenoRx further asserts that Hologic has invented this additional

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[3] The entire construction of disputed language in limitation (e) in *Xoft* reads:

> "rendering uniform"---to make the absorbed dose of radiation more uniform in order to prevent over-treatment of body tissue at or close to the outer wall of the instrument
>
> "Means . . . for rendering uniform the radial absorbed dose profile of the emissions"---
>
> Function: Modifying the ratio of the absorbed dose at a depth of interest in the target tissue to the absorbed dose at the surface of the tissue.
>
> Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate.

Xoft at 10.

limitation that the patent requires conformance between the tissue and the outside surface of the balloon to avoid summary judgment on invalidity.

Hologic, in its opening claim construction brief, argued that uniformity is measured over a "distance from the center of the cavity along a direction of interest" and is characterized by the "flatter" line 42 shown in Figure 4 of the '813 patent. As in the *Xoft* case, Hologic identified the radiation-absorbing or attenuating material as the structure producing the uniformity of the dose profile. Hologic did not assert that the term "uniform" required the surface of the excision cavity to contact the balloon at all points. Even if, as Dr. Verhey testifies, such conformity is necessary to produce a uniform dose profile, that does not justify reading such a requirement into a limitation directed at the absorbed dose distribution as a function of radial distance when the radioactive fluid is contained within the inner chamber and is surrounded by a radiation absorbing material. The "radial absorbed dose profile," therefore, means the absorbed dose as a function of distance in a radial direction from the outer surface of the radiation transparent wall."[4]

It is true that during prosecution of the '813 patent, the patentee distinguished Claim 1 from a prior art patent reference in part because the prior art reference had a banana shape. The banana shape would not provide a uniform radial dose profile because the profile of the shape would be significantly different at the proximal and distal ends of the banana shaped balloon than in its central tissue contacting region. The lack of uniformity and the resulting distinction for prior art purposes, seems to arise not from the lack of tissue contact but from asymmetries in the outer chamber itself.

It may be that a strict conformity is necessary to achieve the most uniform dose profile. But neither the claim nor the intrinsic evidence supports implying such a limitation in Claim 1.

2. The Expandable Outer Surface Element Is . . . Adapted to Contact Tissue . . . and Conform the Tissue. . . .; the Expandable Outer Surface Is Sufficiently Rigid to Deform the Target Tissue

Claim 4 of the '204 patent describes an apparatus with an expandable surface element adapted to contact tissue surrounding a cavity and to conform the tissue to the shape of the expandable surface element. Claim 4 of the '204 patent reads:

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[4] Claim 1(c) does concern the shape of the device volumes, but similarly cannot be read to require conformity between the tissue and the outer chamber.

> The apparatus of claim 3, wherein the expandable surface element is adapted to contact tissue surrounding a resected cavity and adapted to conform the tissue to the desired shape of the expandable surface element.

'204 patent 8:43-46. Claim 8 of the '142 patent requires that an "expandable outer surface is sufficiently rigid to deform the target tissue." Claim 8 states:

> The apparatus of claim 1, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

'142 patent 10:13-17.

The parties argue for the following constructions:

Term	Hologic	SenoRx
"adapted to contact tissue . . . and adapted to conform the tissue"(Claim 4 of '204 patent)	No construction necessary	the expandable outer surface element is capable of contacting the tissue and capable of conforming the tissue. This does not require that the expandable outer surface actually contacts or conforms the tissue.
"expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface" (Claim 8 of '142 patent)	No construction necessary	the expandable outer surface element is sufficiently rigid so as to be capable of deforming tissue. This does not require that the expandable outer surface actually deforms the target tissue.

SenoRx asserts that Dr. Verhey opines for the first time in his expert report that the "adapted to contact tissue . . . and adapted to conform the tissue" language of Claim 4 of the '204 patent requires that the outer balloon to actually contact and conform the tissue. Similarly, SenoRx asserts that Dr. Verhey opines for the first time in his expert report that the "sufficiently rigid to deform" term of Claim 8 of the '142 patent requires that the outer balloon actually deform the tissue.

At the hearing on claim construction, the court became convinced the parties do not, in fact, have any substantive disagreement. Hologic asserts that "adapted to contact tissue" and "adapted to conform the tissue" needs no interpretation. SenoRx submits that "adapted to" means "capable of" and that the claim does not require that the outer balloon actually contact and conform the tissue. Hologic's concern appeared to be that SenoRx was making a distinction between the meaning of

"adapted to" and "capable of" that Hologic did not appreciate and which might later come as a surprise. SenoRx's concern, as mentioned above, was that the outer balloon actually contact and conform the tissue. What became clear at the hearing was that both sides agreed that "[the language] does not require that the expandable outer surface actually contact and conform the tissue." Hearing transcript 138:17-19 (argument of Hologic's counsel).

The prosecution history also supports the conclusion that the outer balloon does not actually have to contact and conform the tissue but it has to be capable of doing so. The "adapted to" wording in Claim 4 resulted from a rejection by the PTO of the exact claim construction plaintiff now asserts is correct. In the prosecution of the '204 patent, the application was rejected for claiming that "the expandable surface element contacts . . . and conforms the tissue." Ex. 20 (June 20, 2000 Office Action, '204 Prosecution History) at 2. The examiner explained that the then proposed language could have been construed as reciting "a positive connection to the body" and suggested the claim instead be amended to read "adapted to" to eliminate this problem. *Id.* As a result, the applicants so amended Claim 4, changing the claim language from "the expandable surface element contacts tissue . . . and conforms the tissue" to "the expandable surface element is adapted to contact tissue . . . and adapted to conform the tissue."

The dispute, to the extent there is one, as to the construction of the language in Claim 8 of the '204 patent—"expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface"— is similar to that involving Claim 4 of the '204 patent. The subject language in Claim 8 requires only requires that the expandable outer surface be sufficiently rigid to deform the target tissue into the shape of the expandable outer surface. It does not necessary have to actually deform the tissue as long as it is capable of doing so.

The court adopts the constructions proposed by SenoRx except that the second sentence in each, which although true, seems unnecessary.

3. Predetermined Asymmetric Isodose Curves

Claims 1 and 8 of the '142 patent requires a "radiation source" to be asymmetrically located so as "to provide predetermined asymmetric isodose curves . . . .", and in the case of Claim 8, sufficiently rigid "to deform the target tissue into the shape of the expandable outer surface . . . ."

SenoRx asserts that Dr. Verhey's seeks to include in the limitation the requirement that the position of the radiation source be capable of being altered or adjusted. The parties word their constructions as follows:

Term	Hologic	SenoRx
"predetermined asymmetric isodose curves"	no construction required	"Predetermined" requires that the asymmetric isodose curves that will be created by the radiation source are determined prior to treatment. It does not require the ability to change the location and arrangement of radiation sources to provide any specific asymmetric isodose curves, but rather determining prior to treatment the isodose curves resulting from the actual asymmetric arrangement and location of the radiation source.

In other words, the parties dispute what is meant by "predetermined." The plain meaning of "predetermined" in the context of Claims 1 and 8 is that the isodose curves that will be created are determined before a particular radiation treatment. The claim does not require that the location or arrangement of the radiation source be capable of being altered or adjusted during a particular treatment with the apparatus.

III. ORDER

For the foregoing reasons, the Court construes the disputed claim language as follows:

Disputed Language	**Court's Construction**
"predetermined spacing"(Claim 1 of '813 Patent and Claim 3 of the '204 patent)	fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (i.e., the inner spatial volume and the outer chamber are concentric and the same shape).
"three-dimensional isodose profile"(Claims 1 and 17 of '204 Patent)	a three-dimensional isodose profile that is a profile with substantially the same shape as the outer spatial volume expandable surface and is concentric with the expandable surface of the outer spatial volume.

"inner spatial volume" (Claim 1 of '813 Patent and Claim 1 of '204 Patent)	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide.
"means . . . for rendering uniform the radial absorbed dose profile . . . ." (Claim 1 of '813 Patent)	Function: making the absorbed dose of radiation more uniform. Structure: a radiation absorbing or attenuating material, e.g., air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents.
"inner closed, chamber" (Claim 11 of '813 Patent)	no construction necessary
"apparatus volume" (Claim 1 of '142 Patent)	*See* Order Denying Partial Summary Judgment of Invalidity of Claims 1 and 8 of '142 patent
"located so as to be spaced apart from the apparatus volume" (Claim 1 of '142 Patent)	*See* Order Denying Partial Summary Judgment of Invalidity of Claims 1 and 8 of '142 patent
"predetermined asymmetric isodose curves" (Claims 1 and 8 of '142 Patent)	isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume. "Predetermined" does not require the ability to change the location and arrangement of radiation sources to provide any specific asymmetric isodose curves
"asymmetrically located and arranged within the expandable surface" (Claim 1 of '142 Patent)	located and arranged inside the expandable surface so as not to be concentric with the expandable outer surface
"plurality" (Claim 12 of '813 Patent and Claim 17 of '204 Patent)	two or more separate radioactive particles placed in the inner spatial volume at the same time; two or more separate radioactive solid sources placed in the inner spatial volume at the same time; two or more separate radioactive solid sources placed within the expandable outer surface at the same time"
"uniform radial absorbed dose profile"; "uniform radiation profile" Claim 1 of '813 Patent)	the absorbed dose as a function of distance in a radial direction from the outer surface of the radiation transparent wall. "Uniform" does not require that the tissue and the balloon conform to each other or relate to the shape of te isodose curve.
"adapted to contact tissue . . . and adapted to conform the tissue" (Claim 4 of '204 Patent)	the expandable surface element is capable of contacting the tissue and capable of conforming the tissue. This does not require that the expandable outer surface actually contact or conform the tissue.
"the expandable outer surface is sufficiently rigid to deform the target tissue"(Claim 8 of '142 Patent)	the expandable outer surface element is sufficiently rigid so as to be capable of deforming tissue. This does not require that the expandable outer surface actually deforms the target tissue.

2/18/09
DATED:

Ronald M. Whyte
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Dated: 2/18/09

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